PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



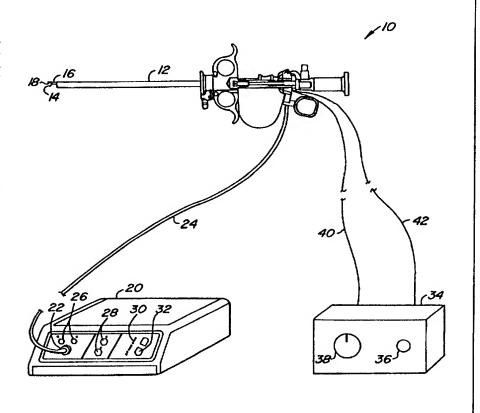
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6: WO 98/00070 (11) International Publication Number: A61B 17/36 A1 (43) International Publication Date: 8 January 1998 (08.01.98) PCT/US97/11604 (81) Designated States: JP, European patent (AT, BE, CH, DE, DK, (21) International Application Number: ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). (22) International Filing Date: 27 June 1997 (27.06.97) **Published** With international search report. (30) Priority Data: 08/678,412 2 July 1996 (02.07.96) US 20 March 1997 (20.03.97) US 08/822,901 (71) Applicant: FEMRX, INC. [US/US]; 1221 Innsbruck Drive, Sunnyvale, CA 94089 (US). (72) Inventors: MILLER, Gary, H.; 529 Bryce Court, Milpitas, CA 95035 (US). SAVAGE, George; 1180 Westridge Drive, Portola Valle, CA 94028 (US). (74) Agents: GIBBY, Darin, J. et al.; Townsend and Townsend and Crew LLP, 8th floor, Two Embarcadero Center, San Francisco, CA 94111-3834 (US).

(54) Title: PREFERENTIALLY INSULATED ELECTRODES AND METHODS FOR USE IN A HOLLOW VISCOUS FILLED WITH A PHYSIOLOGIC FLUID

(57) Abstract

The invention provides methods and apparatus for electro-surgically treating tissue within a hollow viscous which includes a physiologic fluid. According to one exemplary method, a surgical instrument (12) comprising an elongate shaft (16) having a proximal end, a distal end, and an active electrode (14) near the distal end, is introduced into the hollow viscous so that the active electrode is surrounded by the physiologic fluid. Current is then passed between the active electrode and a return electrode while focusing the current from the active electrode so that it passes through a desired region of tissue.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Scnegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav	TM	Turkmenistan
BF	Burkina Faso	GR	Greece		Republic of Macedonia	TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of Americ
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	zw	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's	NZ	New Zealand		
CM	Cameroon		Republic of Korea	PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

PREFERENTIALLY INSULATED ELECTRODES AND METHODS FOR
USE IN A HOLLOW VISCOUS FILLED WITH A PHYSIOLOGIC
FLUID

10

15

20

25

30

35

BACKGROUND OF THE INVENTION

The invention relates generally to the field of electrosurgery, and more particularly to electrosurgical procedures which are performed within a hollow viscous which is filled or distended with a liquid. In one particular aspect, the invention relates to electrosurgical procedures for performing endometrial ablation and resection.

Electrosurgical procedures have become widely used to treat a variety of ailments including those associated with the uterus, such as abnormal uterine bleeding and infertility. Some therapeutic procedures include uterine synechiae resection, endometrial ablation, endometrial resection, submucous myoma resection, intramural myoma resection, transmural myoma resection, and resection of the cervix and the cervical canal. Other electrosurgical procedures include kidney resection (laparoscopy), prostate resection (cystoscopy), ovary resection, removal of lung tissue and tumors (thoracoscopy), and the like. Of these electrosurgical procedures, those dealing with the treatment of the uterus are of particular interest.

Menorrhagia, or abnormal uterine bleeding, is a frequent clinical problem encountered by gynecologists. One common procedure for dealing with such abnormal bleeding is

5

10

15

20

25

30

35

2

through the performance of a hysterectomy. In the United States, it is estimated that about 650,000 hysterectomies are performed each year. However, the performance of hysterectomies is becoming more and more undesirable, especially as new techniques and procedures have been developed to treat abnormal bleeding in a less intrusive manner. For example, a recent development is the use of hysteroscopic surgery employing laser or high frequency electrosurgical energy to destroy or remove the endometrium and a portion of the myometrium using direct visualization. Such procedures have been effective in significantly reducing menstrual blood flow and in decreasing secondary dysmenorrhea. For example, one exemplary device and method for performing both endometrial resection and ablation is described in U.S. Patent No. 5,456,689, the disclosure of which is herein

Patent No. 5,456,689, the disclosure of which is herein incorporated by reference. Other exemplary resection/ablation devices are described in copending U.S. application serial numbers 08/322,680, filed October 13, 1994, (attorney docket number 16944-001100); and 60/008,225, filed November 8, 1995 (attorney docket no. 16944-001200), the complete disclosures of which are herein incorporated by reference.

Such electrosurgical resection/ablation devices are usually configured to employ monopolar current when used within a hollow body cavity, such as the uterus. With monopolar current, the cutting or ablation surface usually consists of an active electrode and a conductive pad return electrode which is applied to the patient's skin. Hence, the current flowing from the active electrode disperses into a low current field which terminates in the return electrode. The return electrode is large enough to reduce the current density to a level that is low enough to prevent the skin from becoming injured (burned) by the return current. Although small, there is some risk that the cutting current traveling from the inside wall of the uterus to the return pad could become concentrated in some delicate tissue, such as the bowel, which happens to be touching the outside of the uterus.

Another concern with the use of electrosurgical procedures within a body cavity such as the uterus is that the

5

10

15

20

25

30

35

3

body cavity usually needs to be distended so that the desired tissue may be adequately visualized and so that enough room is provided to manipulate the surgical instrument. the uterus, an electrically insulated fluid is generally employed. Common non-conductive distention fluids include Sorbitol, Glycine, Sorbitol-Mannitol or Mannitol. such fluids can in certain circumstances pose a danger to the patient. For example, if excessive quantities are absorbed into the patient's circulation, pulmonary edema may result. Further, since such fluids are electrolyte-free, they will, when absorbed in excess, produce plasma dilution of sodium, potassium and other electrolytes. This in turn may produce cardiac problems. Such a fluid may also cause water to transfer into brain cells, producing cerebral edema. Glycine is metabolized in the body and broken down into ammonia. Such a toxic substance can produce disturbances of consciousness, coma, or even death.

To avoid the risk of such complications, fluid loss (the difference between distention fluid used and fluid recovered from the procedure) is carefully monitored during the procedure and distention pressure is controlled to the minimum required for visualization. Such procedures are described in, for example, copending U.S. application serial no. 60/006,408, filed November 9, 1995 (attorney docket no. 16944-000710), the disclosure of which is incorporated herein by reference.

The use of electrolyte solutions to distend the uterus have generally been dismissed for use with electrosurgery since the high frequency current is dispersed in all directions and thereby reduces the possibility of obtaining coagulation or cutting at the tissue/electrode interface. More specifically, when radio frequency current is used within an environment containing a non-conductive fluid, the current supplied to the active electrode passes directly into the tissue contacting the electrode, rather than through the non-conductive fluid. Hence, the power is dissipated within the body in a generally hemispherical pattern.

Moreover, since current is delivered through only a portion of

4

the active electrode, the current density at the active electrode is sufficient to resect or coagulate tissue. When the non-conductive fluid is replaced with a conductive fluid, the power supplied at the active electrode dissipates in a generally spherical pattern. This in turn reduces the current density at the active electrode so that effective resection or coagulation cannot occur. Also, the impedance of tissue increases as the tissue is coagulated. If the surrounding fluid is conductive, very little coagulation will occur since current will preferentially flow through the low impedance fluid rather than through the higher impedance tissue.

Hence, for these and other reasons, it would be desirable to provide systems, methods and apparatus which would provide a safer environment when using electrosurgical procedures, particularly in combination with a distention fluid. Such systems, methods and apparatus should reduce or eliminate the risks associated with the use of nonconductive distention fluids. The systems, methods and apparatus should further prevent or reduce the possibility of unwanted current buildup within the body. In one particular aspect, it would be further desirable to provide systems, methods and apparatus which provide effective resection and coagulation in either conductive or nonconductive distension fluids.

25 SUMMARY OF THE INVENTION

5

10

15

20

30

35

The invention provides systems, methods and apparatus for increasing patient safety during electrosurgical procedures. The systems, methods and apparatus will be particularly useful in performing electrosurgical procedures within a hollow viscous, such as a body cavity or organ, including the uterus, prostatic urethra or the like, which is distended or filled with a fluid.

In one exemplary embodiment, the invention provides a method for treating a hollow viscous which includes a physiologic fluid such as, for example, normal saline solution or a lactated Ringer's solution. According to the method, a surgical instrument comprising an elongate shaft having a proximal end, a distal end, and an active electrode located

near the distal end is introduced into the hollow viscous. When introduced into the hollow viscous, the active electrode is surrounded by the physiologic fluid. Current is passed between the active electrode and a return electrode while focusing the current from the active electrode so that it passes through a desired region of tissue. In this way, the current is directed towards the tissue, rather than dispersing into the physiologic fluid, so that it may be used to cut, desiccate or coagulate the tissue.

5

10

15

20

25

30

35

5

In one aspect of the method, the active electrode is at least partially insulated to focus the current. Insulation of the electrode is further advantageous in that it reduces the surface area of the electrode, thereby reducing the peak power required for resection. Optionally, the active electrode may also be provided with a non-circular cross-sectional shape to provide a region where the current will concentrate.

In one particular aspect, the current is focused by introducing a non-conductive fluid to a selected portion of the electrode. In this manner, the portion of the electrode which is surrounded by the non-conductive fluid will be insulated and will therefore focus the current leaving the electrode.

In another exemplary embodiment, the invention provides a surgical instrument comprising an elongate shaft having a proximal end and a distal end. An active electrode is operably attached to the shaft near the distal end. The instrument includes a means for focusing current from the active electrode so that the current passes through the physiologic fluid and into tissue in a focused pattern.

In one aspect, the means for focusing current comprises insulation covering at least a portion of the active electrode. In another aspect, the means for focusing current comprises a region on the active electrode which is shaped to concentrate the current. Alternatively, the means for focusing current may comprise a combination of insulation covering at least a portion of the active electrode and the shaped region on the electrode. In a further aspect, the

5

10

15

20

25

30

insulation may comprise a non-conductive sheath which may be translated over the electrode to selectively insulate portions of the electrode.

6

According to another exemplary method, a surgical instrument is introduced into the uterus. The surgical instrument comprises an elongate shaft having a proximal end and a distal end, an active electrode near the distal end, and a return electrode. The active electrode is provided with a surface area which is selected to produce a current density sufficient to resect or coagulate tissue. An electrically conductive fluid is also introduced into the uterus to distend the uterus. The active electrode is then activated to produce a magnetic field around the active electrode. In turn, steam which exists between the active electrode and the tissue becomes ionized. Once a sufficient number of ions are present, the steam (which acts as an insulator) is traversed by a spark. Heat radiating from such a spark causes tissue vaporization as well as serving to replenish the steam (which again acts as an insulator). This cycle is rapidly repeated as the active electrode is moved through tissue to resect or coagulate the tissue.

In one aspect, the active electrode will preferably comprise a wire loop having a diameter in the range from about 3 mm to about 12 mm. The wire loop may optionally be provided with rotating spurs or "stars" to provide enhanced coagulation. The return electrode is preferably positioned proximal to the active electrode at a location which is selected so that power produced at the active electrode is dissipated in a focused non-spherical pattern, i.e. in a direction which tends to focus on or move directly toward the return electrode rather than proceeding in a spherical pattern. In this manner, a greater level of current density will be provided in the tissue surrounding the tissue/electrode interface.

In one particularly preferable aspect of the method, the electrically conductive fluid comprises an isotonic irrigation fluid. In another aspect of the method, the surgical instrument further includes the morcellator so that

5

10

15

20

25

30

35

tissue removed by the active electrode may be morcellated. Once morcellated, the tissue will preferably be aspirated through the elongate shaft. In a further aspect, the electrically conductive fluid will preferably be introduced into the body cavity through the elongate shaft.

7

The return electrode may be configured in a variety of ways and may comprise, for example, a pad that is attached to the elongate shaft proximal to the active electrode, a wire coil, the elongate shaft itself, a roller, and the like. this manner, current dispersed from the active electrode will pass through the electrically conductive fluid and to the return electrode, which in turn is attached to the surgical Placement of the return electrode within the body instrument. cavity is advantageous in that it reduces the power dissipation within the conductive fluid, thereby increasing the amount of current in the vicinity of the electrode/tissue interface. Further, when within the body cavity the return electrode will help prevent the concentration of current in unwanted areas. Moreover, by using an electrically conductive fluid, patient safety and comfort is improved by reducing the chance for alteration of the electrolyte balance and/or osmolarity of the blood.

The invention further provides an exemplary system for surgically treating tissue, particularly within the uterus or prostate. The system comprises a surgical instrument having an elongate shaft with a proximal end and a distal end, an active electrode near the distal end, and a return electrode. The system further includes an electrically conductive fluid which may be introduced into a body cavity to form an electrically conductive path between the active electrode and the return electrode when within the body cavity. The active electrode has a surface area which is selected to produce a current density sufficient to resect or coagulate tissue. Further, the return electrode is positioned proximal to the active electrode at a location selected so that the power produced at the active electrode is dissipated in a focused non-spherical pattern.

In one preferable aspect, the electrically conductive fluid comprises an isotonic irrigation fluid. In another aspect, the surgical instrument preferably includes a morcellator for morcellating tissue removed by the active electrode. In still a further aspect, a lumen is disposed through the elongate shaft and an aspiration source is provided for aspirating removed tissue through the elongate shaft. In yet another aspect, the electrically conductive fluid may be introduced into the body cavity through the lumen in the shaft.

The surgical instrument may optionally be provided with a telescope which is operably attached to the shaft so that the active electrode may be visualized through the scope. Optionally, ultrasound may be employed for visualizing tissue within the body cavity. The return electrode will preferably be operably attached to the elongate shaft proximal to the active electrode and may comprise a wire coil, a pad on the elongate shaft, or the elongate shaft itself. The active electrode will preferably comprise a wire loop having a diameter in the range from about 3 mm to about 12 mm.

The invention still further provides an exemplary surgical instrument comprising an elongate shaft having a proximal end and a distal end. An active electrode is operably attached to the shaft near the distal end. A passive return electrode is operably attached to the shaft at a location which is spaced apart from the active electrode. The active electrode has a surface area which is selected to produce a current density sufficient to resect, coagulate or vaporize tissue. Further, the return electrode is positioned at a location selected so that the power produced at the active electrode is dissipated into a much larger surface area as compared to the active electrode.

Preferably, the passive return electrode is formed on the elongate shaft, or may alternatively comprise the shaft itself. The active electrode preferably comprises a wire loop having a diameter in the range from about 3 mm to about 12 mm. The wire loop may optionally be provided with rotating spurs or "stars" to provide enhanced coagulation.

5

10

15

20

25

30

35

9

In another exemplary embodiment, the invention provides a method for surgically treating the uterus. method comprises introducing into the uterus a surgical instrument comprising an elongate shaft having a proximal end and a distal end. The surgical instrument further includes an active electrode, located near the distal end, having a cutting portion and a coagulation or desiccation portion. fluid is introduced into the uterus to distend the uterus. Current is then passed between the active electrode and a return electrode. To resect tissue, the cutting portion of the active electrode is moved along and through the tissue. To coagulate or desiccate tissue, the coagulation or desiccation portion of the active electrode is contacted with In this manner, the same electrode can be used the tissue. for both resection and coagulation or desiccation. example, the electrode may be pulled through tissue to remove a strip of tissue. The electrode may then be re-directed over the remaining tissue for coagulation. In some cases, the leading edge of the electrode may be employed for cutting while the trailing surface is used for coagulation.

In another aspect of the method, the active electrode comprises a wire loop having a diameter in the range from about 3 mm to 12 mm. The active electrode is at least partially insulated so that power produced at the active electrode is dissipated in a focused pattern emanating from the non-insulated portion of the active electrode.

In a still further aspect, the active electrode has a cross-sectional area which includes a major axis and a minor axis, with the major axis being longer than the minor axis. With this arrangement, tissue is cut by moving the electrode through the tissue in a direction generally parallel to the major axis. To coagulate or desiccate tissue, the active electrode is placed against tissue in the region of the minor axis. In some cases, the amount of power supplied to the electrode and/or the type of wave form generated at the electrode may be varied depending on whether cutting or coagulation is needed. For example, for cutting a sinusoidal wave form may be used, while a dampened wave form may be used

to coagulate. Exemplary cross-sectional geometries for the active electrode comprise elliptical or hexagonal geometries.

10

In another aspect of the method, the fluid used to distend the uterus is electrically conductive. Alternatively, the fluid may be non-conductive.

5

10

15

20

25

30

35

In an additional aspect, the shaft is used as the return electrode. In this manner, both the active electrode and the return electrode are inserted into the uterus. Alternatively, the return electrode may comprise a dispersive pad. In this manner, the dispersive pad is placed on the patient's skin outside the uterus.

The invention still further provides an exemplary method for surgically treating the uterus. According to the method, a surgical instrument comprising an elongate shaft having a proximal end, a distal end, and an active electrode near the distal end, is inserted into the uterus. An electrically conductive or non-conductive fluid is introduced into the uterus sufficient to distend the uterus. Current is passed between the active electrode and a return electrode while the active electrode is moved along and through the tissue. At least a portion of the active electrode is insulated so that power produced at the active electrode is dissipated in a focused pattern to resect the tissue.

In another aspect of the method, the active electrode comprises a wire loop having a diameter in the range from about 3 mm to 12 mm. In a further aspect, the insulation covers about 10 percent to about 90 percent of the active electrode.

In another aspect, the active electrode has a cross-sectional area which includes a major axis and a minor axis, such that the major axis is at least as long as the minor axis. To resect the tissue, the cutting portion is moved through the tissue in a direction generally parallel to the major axis. To coagulate or desiccate the tissue, the coagulation or desiccation portion is contacted with the tissue. In this manner, the same electrode can be used for both resection and coagulation or desiccation.

In still another exemplary embodiment, the invention provides a surgical instrument comprising an elongate shaft having a proximal end and a distal end. An active electrode is operably attached to the shaft near the distal end. The active electrode includes a high current density region to resect the tissue when moved along and through the tissue. The active electrode also includes a lower current density region to coagulate or desiccate the tissue when positioned against the tissue.

5

10

15

20

25

30

35

11

In a further aspect of the invention, the active electrode is at least partially insulated so that power produced at the active electrode is dissipated in a focused power dissipation pattern emanating from the non-insulated portion of the active electrode. In another aspect, the active electrode comprises a wire loop having a diameter in the range from about 3 mm to about 12 mm.

In a further aspect, the active electrode has a cross sectional shape with a major axis and a minor axis, wherein the major axis is longer than the minor axis. The high current density region is adjacent the major axis and the lower current density region is adjacent the minor axis. The cross-sectional shape of the electrode may conveniently be configured to be elliptical or hexagonal.

In another aspect, the instrument further comprises a return electrode. In one aspect the return electrode is a dispersive pad located outside the patient. Alternatively, the elongate shaft may be used as the return electrode.

In another exemplary embodiment of the invention, a surgical instrument is provided which comprises an elongate shaft having a proximal end and a distal end. An active electrode is operably attached to the shaft near the distal end. At least a portion of the active electrode is insulated so that power produced at the active electrode is dissipated in a focused power dissipation pattern.

In one aspect, the instrument includes insulation that covers about 10 percent to about 90 percent of the active electrode. In a further aspect, the active electrode

5

15

30

comprises a wire loop having a diameter in the range from about 3 mm to about 12 mm.

In a further aspect, the instrument's active electrode includes a high current density region to resect the tissue when moved along and through the tissue and a lower current density region to coagulate or desiccate the tissue when positioned against the tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

- Fig. 1 illustrates an exemplary system for electrosurgically treating tissue in an environment having an electrically conductive fluid according to the present invention.
 - Fig. 2 is a side view of an exemplary electrosurgical device of the system of Fig. 1.
 - Fig. 3 is a side view of the body of the device of Fig. 2 having its sheath removed.
 - Fig. 4 is a side view of the sheath of the device of Fig. 2.
- Fig. 5 is a side view of the handle of the device of Fig. 2.
 - Fig. 6 illustrates an alternative embodiment of the device of Fig. 2 having a coil as the return electrode according to the present invention.
- Fig. 7 illustrates an alternative embodiment of the morcellator shaft of the device of Fig. 2 having a return electrode pad thereon according to the present invention.
 - Fig. 8 illustrates a roller ball having an active electrode and a return electrode which may be used in non-conductive fluid according to the present invention.
 - Fig. 9 illustrates the device of Fig. 2 being used to electrosurgically treat the uterus when distended with an electrically conductive fluid according to the present invention.

13

Figs. 10A-C are three cross-sectional schematic views of alternative active electrode designs.

Fig. 11 is a perspective view of a particularly preferable active electrode according to the present invention.

Fig. 12A is a cross-sectional view of the active electrode of Fig. 11.

Figs. 12B and 12C illustrate the electrode of Fig. 12A with different cross-sectional geometries.

10 Fig. 13A is a top view of an alternative active electrode design according to the invention.

Fig. 13B is a cross-sectional side view of the electrode of Fig. 13A taken along lines B-B.

Fig. 13C is an end view of the electrode of Fig.

15 13A.

20

25

30

5

Fig. 14A is a top view of yet another alternative active electrode design according to the invention.

Fig. 14B is a cross-sectional side view of the electrode of Fig. 14A taken along lines B-B.

Fig. 14C is an end view of the electrode of Fig. 14A.

Fig. 15A is a top view of still another alternative active electrode design according to the invention.

Fig. 15B is a cross-sectional side view of the electrode of Fig. 15A taken along lines B-B.

Fig. 15C is an end view of the electrode of Fig. 15A.

Figs. 16A-16C are top views of an alternative electrode design having a movable non-conductive sheath according to the invention.

Figs. 17 is a top view of another alternative electrode design having both a non-conductive sheath and apertures for introducing a non-conductive fluid to a portion of the electrode.

Figs. 18A and 18B are top views of still another alternative electrode design having a non-conductive deployable sheath through which a non-conductive fluid may be dispensed onto a portion of the electrode.

14

Fig. 19 is a top view of still another alternative electrode design having a vision system surrounded by apertures to deliver a non-conductive fluid to a portion of the electrode.

Fig. 20 is a top view of yet another alternative electrode design having a vision system and an outer tube for delivering a non-conductive fluid to a portion of the electrode.

5

10

15

20

25

30

35

DETAILED DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The invention provides methods, systems and apparatus for electrosurgically treating tissue. The methods, systems and apparatus will preferably be used to treat tissue located within a body cavity or organ that is filled or distended with a distention fluid. Although useful in a variety of body cavities or organs, the invention will find its greatest use in electrosurgically treating the endometrial lining of the uterus. However, it will be appreciated that the invention may be useful in the fields of urology, cardiology, radiology, gynecology, laparoscopy and the like.

The distention medium will preferably comprise an electrically conductive fluid such as saline, Ringer's Lactate Solution, or the like which do not significantly alter the electrolyte balance of the blood. In this manner the risk of cerebral edema, and other risks which may arise if the distention medium passes into the blood stream can be greatly reduced or eliminated. In some cases, however, a non-conductive fluid may be used.

Apparatus according to the invention will, in one preferable aspect, comprise an active electrode such as an electrosurgical cutting wire or loop, and may include ablation spurs or "stars" as described in copending U.S. Application Serial No. 60/008,225, previously incorporated by reference. The device will further include a "passive" return electrode which is preferably attached to the electrosurgical instrument so that it is also within the body cavity during treatment. The return electrode will preferably have a surface area that is substantially greater than the surface area of the active

5

10

15

20

25

30

35

15

electrode so that the current density level at the return electrode is significantly less than at the active electrode. Moreover, the return electrode is preferably positioned proximal to the active electrode at a location selected so that power produced at the active electrode is dissipated in a pattern which is intended to approximate a focused power dissipation pattern where the dissipated power travels in a direction which is directed toward the return electrode rather than proceeding in a spherical pattern. In this manner, highly concentrated current will be produced at the active electrode/tissue interface so that cutting and/or ablation may occur at the active electrode. Higher current densities are also provided at the tissue/electrode interface by reducing the size of the active electrode. Preferably, the active electrode will comprise a wire loop having a diameter in the range from about 3 mm to about 12 mm.

The current that is dispersed into the conductive distention fluid concentrates on the return electrode. Due to the large surface area of the return electrode, the return current has the low enough current density so that it will not cut, coagulate, or otherwise harm tissue located within the body cavity.

The invention alternatively provides a system and method for treating a hollow viscous, such as a cavity or sinus, which includes physiologic fluid. According to the invention, an instrument comprising an elongate shaft having a proximal end and a distal end is introduced into the hollow viscous. An active electrode, located near the distal end, is surrounded by the physiologic fluid when in the hollow viscous. Current is passed between the active electrode and a return electrode, while focusing the current from the active electrode so that it is directed into tissue in a focused pattern.

To focus the current into the desired region, the active electrode may be at least partially insulated. In this manner, the non-insulated portion of the active electrode can be oriented to focus current into the desired region. Further, use of insulation reduces the peak power needed for

resection. Alternatively, the active electrode may have a non-circular cross-sectional shape. In this manner, the current is concentrated on a region of the electrode which may be used to cut or coagulate tissue. The active electrode may also include a combination of insulation and non-circular cross-sectional shape in order to focus the current.

5

10

15

20

25

30

35

16

Referring now to Fig. 1, an exemplary system 10 for electrosurgically treating tissue will be described. 10 includes a surgical instrument 12 for electrosurgically treating tissue and will be described in greater detail hereinafter. Briefly, surgical instrument 12 includes an active electrode 14 which may be used to cut and/or ablate tissue, and a morcellator shaft 16 having a morcellator 18 which is spaced apart from active electrode 14. A drive unit 20 is provided to rotate morcellator shaft 16. Drive unit 20 includes a variety of controls including a drive cable output 22 for connection to a drive cable 24, directional control switches 26, enable/stop switches 28, LED readout switches 30, and speed control switches 32. System 10 further includes an electrosurgery generator unit (ESU) 34 which supplies high frequency electrical current to active electrode 14. includes an enable switch 36 and a power control switch 38. Current is supplied to active electrode 14 through a line 40, while a line 42 provides a return path back to ESU 34.

Referring now to Figs. 2 and 3, construction of surgical instrument 12 will be described in greater detail. As previously described, surgical instrument 12 includes active electrode 14 and morcellator shaft 16. Active electrode 14 is fashioned in the form of a wire loop which is in electrical communication with line 40 (See Fig. 1). Wire loop when insulated may optionally be provided with spurs, stars, cylinders, or the like which may be rotated as described in co-pending application serial no. 60/008,225 to enhance coagulation. Electrode 14 preferably has a diameter in the range from about 3 mm to about 12 mm. Morcellator shaft 16 has a lumen extending therethrough so that tissue removed by morcellator 18 may be aspirated through the lumen. Surgical instrument 12 further includes a handle 44 which

5

10

15

20

25

30

35

provides a convenient grip for the surgeon. A sheath 46 which is preferably non-conductive provides a protective cover for morcellator shaft 16.

Morcellator shaft 16 is attached to a resector body 48 having a thumb ring 50. Thumb ring 50 and handle 44 cooperate together to axially translate active electrode 14. More specifically, a return spring 52 is placed between handle 44 and thumb ring 50 to bias thumb ring 50 away from handle As the surgeon squeezes thumb ring 50 toward handle 44, active electrode 14 is translated forward. As the surgeon relaxes his hand, thumb ring 50 is slowly translated away from handle 44 with assistance from return spring 52 to slowly translate active electrode 14 back toward handle 44. telescope 54 is conveniently provided to allow viewing of active electrode 14 during the procedure. As best shown in Fig. 5, handle 44 includes a scope mount 56 for holding scope Optionally, an ultrasonic transducer may be employed along with telescope 54 (or in some cases may be used in place of telescope 54) to visualize tissue within the body cavity. Use of ultrasound is described in copending application serial no. 08/322,680, previously incorporated by reference. shown in Fig. 2, a light cable 63 is provided for connecting a light source to telescope 54 so that the body cavity may be illuminated.

As shown in Fig. 3, surgical instrument 12 employs morcellator shaft 16 as the return electrode. By having electrode 14 extend from shaft 16, power produced at a distal portion of electrode 14 dissipates distally outward in a focused non-spherical pattern into the uterine tissue. As shown in phantom line, current leaving a proximal portion of active electrode 14 passes through the electrically conductive medium in a generally direct line where it concentrates on the entire morcellator shaft 16. In this manner, the amount of power dissipated into the conductive irrigation solution is reduced so that as electrode 14 is proximally translated through tissue, the proximal portion in contact with the tissue will have a current density sufficient to cut or coagulate the tissue. Due to the large surface area of

morcellator shaft 16, the current density at morcellator shaft 16 will be at a safe level so that if morcellator shaft 16 engages tissue, the tissue will not be harmed. Morcellator shaft 16 is constructed of an electrically conductive material such as stainless steel, and is in electrical communication with return line 42 (See Fig. 1). Alternatively, surgical instrument 12 could be constructed so that sheath 46 serves as the passive return electrode. However, sheath 46 will preferably be non-conductive to maximize patient safety.

As best shown in Figs. 2 and 4, surgical instrument 12 includes an irrigation connector 58 through which the electrically conductive media is introduced into the body cavity. An inflow valve 60 may be employed to control the volume of fluid flowing into the body cavity. When the body cavity is sufficiently distended, inflow valve 60 may be closed to maintain the fluid pressure within the body cavity. As shown in Fig. 2, a fluid tube 62 is provided on surgical instrument 12 and is in fluid communication with the lumen extending through morcellator shaft 16 so that morcellated tissue can be aspirated from the body cavity. A stopcock valve having a handle 65 is provided for preventing the flow of fluid through tube 62.

Referring now to Fig. 6, an alternative embodiment of a surgical instrument 64 will be described. Surgical instrument 64 is essentially identical to surgical instrument 12 of Fig. 2 except for the configuration of the passive return electrode. More specifically, surgical instrument 64 includes a return electrode 66 which is constructed in the form of a wire coil. Return electrode 66 is held within a non-conductive housing 68 which is attached to the instrument opposite irrigation connector 58. Return line 42 is connected to return electrode 66 to complete the electrical circuit. As configured, electrical current from active electrode 14 passes through the electrically conductive medium within the sheath and to the return electrode 66.

Referring to Fig. 7, an alternative embodiment of a morcellator shaft 70 for use with surgical instrument 12 will be described. Morcellator shaft 70 is essentially identical

5

10

15

20

25

30

35

to morcellator shaft 16 of Fig. 3 except that morcellator shaft 70 includes a dispersive pad 72 attached thereto in the vicinity of active electrode 14. Preferably, pad 72 will be located within about 5 mm to about 50 mm of electrode 14. Return line 42 is in electrical communication with dispersive pad 72 allowing dispersive pad 72 to function as the passive return electrode. In this manner, current leaving active electrode disperses through the conductive medium and concentrates on dispersive pad 72 where the current density is sufficiently low to provide a safe working environment. Further, the distance between pad 72 and electrode 14 is selected such that the power dissipated within a conductive distention fluid will concentrate on pad 72 to form a focused non-spherical dissipation pattern. In this way, a higher level of current is provided at the tissue/electrode interface.

Referring to Fig. 8, an alternative embodiment of an active electrode 74 will be described. Active electrode 74 is included on a roller 76 which in turn includes a return electrode 78. Electrodes 74 and 78 are separated by an insulating spacer 80. The surface area of active electrode 74 and return electrode 78 are approximately equal so that the current densities at both the active electrode 74 and return electrode 78 will be approximately the same. To treat tissue, roller 76 is rolled along the tissue with electrodes 74 and 78 ablating the contacted tissue. Roller 76 will preferably be used in a non-conductive distention medium. Roller 76 will conveniently be attached to a shaft (not shown) and may be provided with irrigation and aspiration sources similar to those previously described with surgical instrument 12.

An alternative electrosurgical device which may be used in an electrically conductive medium comprises a pair of closely spaced needle electrodes. Such a device is operated in a bipolar manner, with the current passing between the two needles. A ball may optionally be provided on each of the needles to control the depth of the needles within the tissue.

Referring now to Fig. 9, an exemplary method for performing endometrial resection/ablation with surgical

20

instrument 12 will be described. Initially, sheath 46 is introduced to the uterus U through the cervical canal C with an obturator (not shown). The obturator is then removed and morcellator shaft 16 is introduced through sheath 46 until active electrode 14 and morcellator 18 are exposed within the uterus U. Inflow valve 60 is then opened and an electrically conductive irrigation fluid is delivered through irrigation connector 58. The uterus U is filled with the distention fluid until the uterus U is sufficiently distended.

5

10

15

20

25

30

35

Electrical current is then provided to active electrode 14 whereupon active electrode 14 is translated back and forth by manipulating handle 44 and thumb ring 50 as previously described. Active electrode 14 is moved along and through tissue to remove and/or ablate the endometrial lining. Any removed tissue is chopped into smaller morsels by morcellator 18. The morsels in turn are removed through morcellator shaft 16 through tube 62. As fluid is withdrawn through tube 62, new fluid is introduced so that the uterus U maintains its distended configuration. To monitor the amount of fluid within the uterus U, a flow device, such as that described in copending U.S. application serial no. 60/006,408, previously incorporated by reference, may be used.

When distending the uterus with the electrically conductive fluid, a safer working environment is provided since the body can more safely handle the absorption of the electrically conductive fluid. Moreover, by employing morcellator shaft 16 as the return electrode, a safe working environment is provided with the uterus since the current leaving active electrode 14 will be dispersed through the electrically conductive fluid and will concentrate on shaft 16, rather than propagating through surrounding organs or tissue, such as the bowel, en route to a dispersive electrode located on the skin. In the event that shaft 16 inadvertently touches tissue, the current density will be sufficiently low so that such tissue will not be harmed. Moreover, by employing an active electrode with a relatively small surface area and a return electrode proximal to the active electrode, a high level of current is produced at the active electrode so

5

10

15

20

25

30

35

that tissue surrounded by a conductive medium may effectively be resected and/or coagulated.

21

An alternative active electrode may be used to focus the current so that the electrode will be able to provide electrosurgical functions in a physiologic fluid which may be either electrically conductive or non-conductive. electrode may also be configured to both resect and coagulate tissue, depending on the orientation of the electrode with respect to the tissue, or depending on the power settings and/or the particular type of wave form. To accomplish resection or coagulation with the same electrode, the electrode is configured to have a high current density region for cutting tissue and a lower current density region for coagulating tissue. When the high current density region contacts the tissue, resection occurs, and when the lower current density region contacts the tissue, coagulation The active electrode may have both high and lower current density regions by controlling the amount of insulation placed on the electrode and/or by altering the shape of the electrode.

The configuration of an electrode so that it will focus the current is illustrated schematically in Figures 10A-Figure 10A shows a schematic representation of an active electrode 100 comprising a round wire 102 containing an electrically conductive portion 110 and a non-conductive portion 112. The non-conductive portion 112 is larger than the conductive portion 110, resulting in an exposed surface area 106 which is less than one-half of the entire surface area of the wire 102. By using a non-conductive portion 112, current dissipates only through the exposed surface 106 of the conductive portion 110. In this way the current is focused so that it will pass into the tissue with electrosurgical capabilities, rather than dissipating into the fluid within the cavity or sinus. Further, by reducing the electrode surface area, i.e. exposed surface 106, the current density is increased, thereby decreasing the peak power required to perform the resection or coagulation.

Figures 10B and 10C present schematic views of the active electrode 100 of Figure 10A flattened by 25 percent and 50 percent, respectively. Figures 10B and 10C show the use of both insulation and electrode shape to control the current dissipation pattern. Flattening the wire 102 creates a cross-sectional shape with a major axis which is longer than the minor axis. By flattening the active electrode, the current tends to concentrate at the ends of the major axis, with the concentration of current being controlled by the degree of flatness. With such a configuration, tissue may be resected by moving the electrode along and through tissue in a direction generally parallel to the cross-sectional major axis where the current density is at its greatest.

Coagulation or desiccation of tissue occurs by contacting the tissue with the low current density region of the electrode while moving the active electrode in a direction generally parallel to the cross-sectional major axis. In this manner, the portion of the exposed surface area 106 with a lower current density contacts the tissue to cause coagulation or desiccation without resecting the tissue. As a result, the same active electrode can be use to resect, coagulate or desiccate tissue depending on which portion of the exposed surface area 106 contacts the tissue. Further electrosurgical function may be tailored by varying the amount of power supplied to the electrode and/or by varying the type of wave form.

Referring now to Figure 11, a preferred embodiment of an active electrode which may be used with any of the instruments described herein will be described. Active electrode 120 comprises a round wire 122 having a diameter preferably ranging from about 0.005 inches to about 0.100 inches. The active electrode 120 has a loop portion 123 which is partially insulated with insulation 124. Insulation 124 preferably covers from about 10 percent to about 90 percent of the wire's surface area. Since loop portion 123 is only partially insulated, an exposed surface 126 of the active electrode 120 is provided. The exposed surface 126 of loop

PCT/US97/11604 WO 98/00070

23

5

10

15

20

25

30

35

portion 123 may be used for resection, coagulation and/or desiccation as described hereinafter.

Figure 12A shows a cross-sectional side view of active electrode 120. When current is flowed through wire 122, current is dissipated from exposed surface 126. Since the wire is preferentially insulated, the current flowing from exposed surface 126 is focused or directed towards the tissue In this way, electrode 120 may be used in a to be resected. conductive medium, with the current being focused toward the tissue rather than dispersing into the medium. In this way, exposed surface 126 may simply be moved along and through tissue to resect the tissue. Further, since the preferential insulation reduces the surface area of the wire, the peak power required for resection will be reduced. appreciated that the amount of current flowing through electrode 120 may be reduced for applications requiring coagulation or desiccation of the tissue. Hence, by reducing the power level and placing exposed surface 126 against tissue, the tissue will be coagulated or desiccated.

Figures 12B and 12C illustrate electrode 120 when flattened by 25% and 50%, respectively, it being appreciated that active electrode 120 may be flattened by other percentages. As active electrode 120 is flattened, a major and a minor axis are created. With such a configuration, the current will tend to concentrate near the ends of the major In this way, exposed surface 126 is provided with both a cutting portion and a coagulation or desiccation portion. Since the current density will be at its greatest near the ends of the major axis, electrode 120 may be passed along and through tissue in a direction generally parallel to the major Electrode 120 may also be used to coagulate or desiccate tissue by simply placing the low current region of electrode 120 against tissue and moving the electrode in a direction generally parallel to the major axis.

Figs. 13A-13C illustrate an alternative electrode design 130 which may be used with any of the instruments described herein. Electrode 130 comprises a pair of shaped fingers 132 and 134 which allow electrode 130 to operate in a

24

bipolar manner. As shown in Fig. 13B, fingers 132 and 134 are shaped and preferably insulated with insulation 136 to focus the current similar to the electrode designs previously described herein. In this manner, electrode 130 may be used with both physiologic fluids and non-conductive fluids. Further, by shaping the electrodes and providing insulation, electrode 130 may be employed to both cut and coagulate tissue in a manner similar to that previously described with other embodiments. Hence, it will be appreciated that fingers 132 and 134 may be shaped and preferentially insulated in ways similar to that previously described with other embodiments.

5

10

15

20

25

30

35

One particular advantage of employing electrode design 130 is that the use of a plurality of fingers increases the number of cutting edges and thereby increases the effective cutting or desiccation surface area of the electrode. As with previous embodiments, the exposed area of fingers 132 and 134 may be adjusted to adjust the current density at the electrode surface.

Alternatively, fingers 132 and 134 may be electrically connected to act as a single electrode. In this manner, fingers 132 and 134 may be used in connection with a dispersive pad or other return electrode as described with previous embodiments.

Although shown with two fingers, it will be appreciated that additional fingers may be provided to an electrode design to further increase the number of cutting or desiccation edges. For example, in Figs. 14A-14C an electrode design 140 is provided with four shaped fingers 142, 144, 146 and 148. However, it will be appreciated that virtually any number of fingers may be provided depending upon the particular need and the required surface area. As with the embodiments in Fig. 13, the fingers of electrode design 140 will preferably be shaped and/or preferentially insulated with insulation 149 to focus current similar to that previously described.

Figs. 15A-15C illustrate another alternative electrode 150 which may be employed with any of the surgical instruments described herein. Electrode 150 is configured to

operate in bipolar manner in either a physiologic fluid or a non-conductive fluid. Electrode 150 includes a U-shaped distal end 152 which is separated by insulation 154. In this manner, half of electrode 150 serves as the active electrode while the other half serves as the return electrode. As shown in Fig. 15B, electrode 150 will preferably be shaped and/or preferentially insulated with insulation 156 similar to previous embodiments to focus current in order to enhance electrosurgical function.

With any of the embodiments shown in Figs. 13-15, a stiffening bridge may be placed between some or all of the fingers. In this way, the bridge will enhance the physical integrity of the electrodes. The bridge may be either electrically insulated or non-insulated. In this manner, depending on the electrical hook-ups, bridge positions and bridge materials, the embodiments may be operated in a monopolar, focused monopolar or bi-polar mode as previously described herein.

Figs. 16A-16C illustrate yet another alternative embodiment of an electrode 160 which may be employed with any of the surgical instruments described herein, and will be particularly useful in a hollow viscous which is filled with a conductive medium. Electrode 160 includes a movable nonconductive sheath 162 which may be advanced over electrode 160 to selectively vary the exposed portion of electrode 160. In this manner, a user may preferentially insulate electrode 160 by simply advancing sheath 162 in a distal direction as illustrated in Figs. 16B and 16C. Hence, by changing the exposed surface area of electrode 160, the current may be focused in order to enhance electrosurgical function as previously described herein.

Sheath 162 will preferably be configured to be translated over electrode 160 from outside the patient. With this configuration, a user may change the amount of exposed area on electrode 160 at any time while performing a procedure. Exemplary non-conductive materials that may be used to construct sheath 162 comprise thermoplastics, thermosets, siloxances and the like.

Fig. 17 illustrates another alternative embodiment of an electrode 164 which is useful in a conductive medium environment. Electrode 164 includes a deployable sheath 166 which is similar to the sheath 162 of electrode 160 as previously described. Electrode 164 further includes a central lumen and a plurality of apertures 168 through which a non-conductive fluid, such as glycine, may be introduced as illustrated by arrows 170. In this manner, sheath 166 may be employed to adjust the surface area of electrode 164 as previously described, and a non-conductive fluid may also be introduced to a selected portion of electrode 164. The non-conductive fluid serves to preferentially insulate the selected portion in order to focus current and to enhance electrosurgical function in a manner similar to that previously described herein.

Referring now to Figs. 18A and 18B, still another alternative embodiment of an electrode 172 will be described. Electrode 172 includes a non-conductive deployable sheath 174 which is similar to the sheaths in the embodiments previously described. Sheath 174 further includes at least one lumen through which a non-conductive fluid may be passed so that the non-conductive fluid will be introduced to a portion of electrode 172 as illustrated by arrows 176. In this way, sheath 174 may be employed to vary the exposed area of the active electrode while also being employed to introduce a non-conductive fluid to a portion of electrode 172 to focus the current and to enhance electrosurgical function.

Shown in Fig. 19 is an alternative embodiment of an electrode 178 having a vision system 180. Vision system 180 preferably comprises an elongate scope and is employed to allow a user to visualize electrode 178 from outside the patient while performing a surgical procedure. Passing adjacent vision system 180, i.e. around its periphery, is at least one lumen through which a non-conductive fluid may be passed to introduce the non-conductive fluid to at least a portion of electrode 178 as illustrated by arrows 179. In this way, electrode 178 may be preferentially insulated to

27

focus current in a manner similar to that previously described.

5

10

15

20

As shown in Fig. 20, electrode 178 may be modified to include an external tube 182 through which a non-conductive fluid may be passed to introduce the fluid to electrode 178 as illustrated by arrows 179.

The embodiments which are configured to deliver a non-conductive fluid to the active electrode, as described above, preferably further include a pump, compressor, tank or the like to supply the physician with pressurized fluid. A solenoid valve or other actuator is also provided to control the supply of the pressurized, non-conductive fluid so that it may be dispensed onto the electrode. The solenoid valve is coupled to the electrosurgical generator so that when power is supplied to the electrode, the solenoid valve will be actuated to deliver the non-conductive fluid to the electrode.

The invention has now been described in detail. However, it will be appreciated that certain changes and modifications may be made. Therefore, the scope and content of this invention are not limited by the foregoing description. Rather, the scope and content are to be defined by the following claims.

WHAT IS CLAIMED IS:

 A method for treating a hollow viscous which includes a physiologic fluid, the method comprising:

introducing into the hollow viscous a surgical instrument comprising an elongate shaft having a proximal end, a distal end, and an active electrode near the distal end, wherein the active electrode is surrounded by the physiologic fluid; and

passing current between the active electrode and a return electrode while focusing the current from the active electrode so that it passes through a desired region of tissue.

- 2. A method as in claim 1, further comprising moving the electrode along and through the tissue, wherein at least a portion of the active electrode is insulated so that power produced at the active electrode is dissipated in a focused pattern to resect the tissue.
- 3. A method as in claim 1, wherein the active electrode has a non-circular cross-sectional shape to focus the current, wherein the active electrode is elliptical in geometry, and wherein the active electrode includes a cutting portion and a coagulation or desiccation portion.
- 4. A method for surgically treating the uterus, the method comprising:

introducing into the uterus a surgical instrument comprising an elongate shaft having a proximal end, a distal end, and an active electrode near the distal end, wherein the active electrode includes a cutting portion and a coagulation or desiccation portion;

9 introducing a fluid into the uterus sufficient to distend the uterus;

passing current between the active electrode and a return electrode; and WO 98/00070 29

PCT/US97/11604

13 moving the cutting portion of the active electrode 14 along and through the tissue to resect the tissue, and 15 contacting the coagulation or desiccation portion of the active electrode with the tissue to coaqulate or desiccate the 16

- 5. A method as in claim 4, wherein the active 1 2 electrode comprises a wire loop and is at least partially insulated so that power produced at the active electrode is 3 dissipated in a focused pattern. 4
- 1 A method as in claim 2 or 4, wherein the active 2 electrode has a cross-sectional area which includes a major 3 axis and a minor axis, wherein the major axis is longer than 4 the minor axis, wherein moving the cutting portion through the tissue comprises moving the active electrode in a direction 5 6 generally parallel to the major axis, and wherein contacting 7 the coaquiation or desiccation portion with the tissue comprises contacting the active electrode with the tissue 8 adjacent the minor axis. 9
 - 7. A method for treating a hollow viscous which includes a physiologic fluid, the method comprising: introducing into the hollow viscous a surgical instrument comprising an elongate shaft having a proximal end, a distal end, and an active electrode near the distal end,
- 5 6 wherein the active electrode is surrounded by the physiologic fluid; and 7

passing current between the active electrode and a return electrode while introducing a non-conductive fluid to a portion of the active electrode, wherein the current is focused so that it passes through a desired region of tissue.

- 1 A surgical instrument, comprising:
- 2 an elongate shaft having a proximal end and a distal
- 3 end;

17

1

2 3

4

8 9

10 11

tissue.

4 an active electrode operably attached to the shaft 5 near the distal end; and

- a means for focusing current from the active
 electrode so that the current will pass through a physiologic
 fluid and into tissue in a focused pattern.
- 9. A surgical instrument as in claim 8, wherein the means for focusing current comprises insulation which covers at least a portion of the active electrode or a region on the electrode which is shaped to concentrate the current.
- 1 10. A surgical instrument, comprising:
 2 an elongate shaft having a proximal end and a distal
 3 end; and

an active electrode operably attached to the shaft near the distal end, wherein the active electrode comprises a high current density region to resect the tissue when moved along and through the tissue and a lower current density region to coagulate or desiccate the tissue when positioned against the tissue.

- 11. An instrument as in claim 10, wherein the active electrode comprises a wire loop which is at least partially insulated so that power produced at the active electrode is dissipated in a focused power dissipation pattern, and further comprising a return electrode which comprises a dispersive pad outside the patient or the elongate shaft.
- 12. An instrument as in claim 1, wherein the active electrode has a cross sectional shape which includes a major axis and a minor axis, wherein the major axis is longer than the minor axis, and wherein the high current density region is adjacent the major axis and the lower current density region is adjacent the minor axis.
- 1 13. A surgical instrument, comprising:
 2 an elongate shaft having a proximal end and a distal
 3 end; and

WO 98/00070 - 31

an active electrode operably attached to the shaft near the distal end;

6 wherein at least a portion of the active electrode

7 is insulated so that power produced at the active electrode is

PCT/US97/11604

8 dissipated in a focused power dissipation pattern.

- 1 14. An instrument as in claim 13, wherein the
- 2 insulation covers about 10 percent to about 90 percent of the
- 3 active electrode, wherein the active electrode comprises a
- 1 wire loop.
- 1 15. An instrument as in claim 13, wherein the
- 2 active electrode has a cross sectional shape which includes a
- 3 major axis and a minor axis, wherein the major axis is at
- 4 least as long as the minor axis, wherein the active electrode
- 5 comprises a high current density region to resect the tissue
- 6 when moved along and through the tissue and a lower current
- 7 density region to coagulate or desiccate the tissue when
- 8 positioned against the tissue.
- 1 16. A surgical instrument, comprising:
- an elongate shaft having a proximal end and a distal
- 3 end;
- an active electrode operably attached to the shaft
- 5 near the distal end; and
- a fluid delivery mechanism disposed to introduce at
- 7 least one stream of a non-conductive fluid to a portion of the
- 8 active electrode to focus current from the active electrode so
- 9 that the current will pass through a physiologic fluid and
- 10 into tissue in a focused pattern.
- 1 17. An instrument as in claim 16, further
- 2 comprising a non-conductive sheath slideably received over the
- 3 active electrode, wherein the electrode may be selectively
- 4 insulated by covering portions of the electrode with the
- 5 sheath.

32

18. A method for surgically treating the uterus, the method comprising:

8

9

10

11 12

13

14 15

18

19

20

21 22 introducing a surgical instrument comprising an elongate shaft having a proximal end and a distal end, an active electrode near the distal end, and a return electrode into the uterus;

introducing an electrically conductive fluid into the uterus sufficient to distend the uterus and to form an electrically conductive path between the active electrode and the return electrode;

16 contacting the active electrode against tissue 17 within the uterus;

passing current between the active electrode and the return electrode while the active electrode is contacting the tissue, wherein the active electrode has a surface area which is selected to produce a current density sufficient to resect or coagulate the tissue; and

moving the active electrode along and through the tissue to resect, coagulate or vaporize the tissue.

- 19. A method as in claim 18, wherein the active electrode comprises a wire loop having a diameter in the range from about 3 mm to about 12 mm, and wherein the return electrode is positioned proximal to the active electrode at a location selected so that power produced at the active electrode is dissipated in a focused non-spherical power dissipation pattern.
- 20. A method as in claim 18, wherein the electrically conductive fluid comprises an isotonic irrigation fluid which is introduced into the uterus through the elongate shaft, wherein the surgical instrument includes a morcellator, further comprising morcellating the tissue removed by the active electrode, and further comprising aspirating the removed tissue through the elongate shaft.
- 21. A method as in claim 18, wherein the return electrode comprises an electrode pad which is operably

attached to the elongate shaft proximal to the active

4 electrode, a wire coil or the elongate shaft.

22. A method for surgically treating a body organ,
the method comprising:

introducing a surgical instrument comprising an elongate shaft having a proximal end and a distal end, an active electrode near the distal end, and a return electrode into the body organ;

introducing an electrically conductive fluid into the body organ to form an electrically conductive path between the active electrode and the return electrode;

10 contacting the active electrode against tissue 11 within the body organ;

passing current between the active electrode and the return electrode while the active electrode is contacting the tissue, wherein the active electrode has a surface area which is selected to produce a current density sufficient to resect, coagulate or vaporize the tissue; and

moving the active electrode along and through the tissue to resect, coagulate or vaporize the tissue.

23. A surgical instrument, comprising:

an elongate shaft having a proximal end and a distal end;

an active electrode operably attached to the shaft near the distal end; and

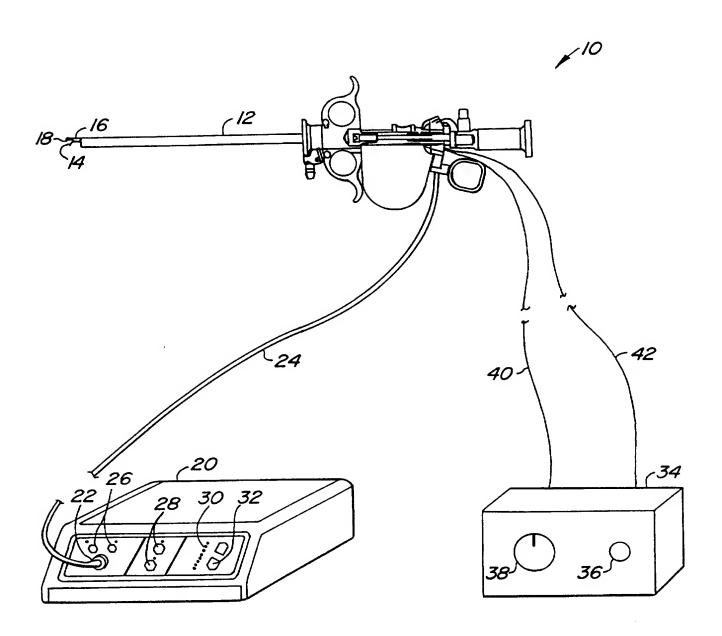
a passive return electrode operably attached to the shaft at a location which is spaced-apart from the active electrode;

wherein the active electrode has a surface area which is selected to produce a current density sufficient to resect, coagulate or vaporize the tissue when placed in an electrically conductive irrigation fluid, and wherein the return electrode is positioned proximal to the active electrode at a location selected so that power produced at the active electrode is dissipated in a focused non-spherical power dissipation pattern.

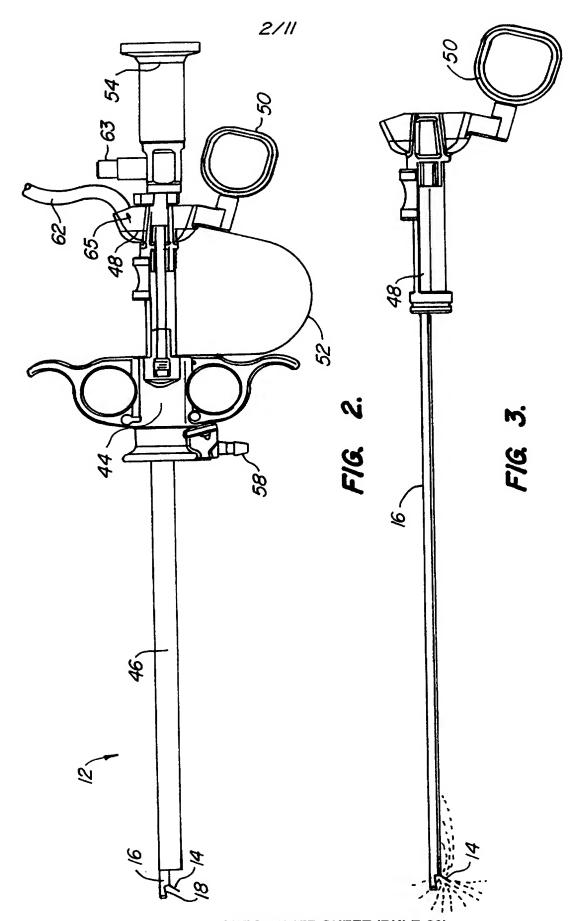
24. An instrument as in claim 23, wherein the active electrode includes an active surface, wherein the passive electrode includes a passive surface, and wherein the surface area of the active surface is less than the surface area of the passive surface so that a greater power density is produced at the active surface relative to the passive surface.

- 25. An instrument as in claim 23, wherein the passive return electrode is formed on the elongate shaft, wherein the active electrode comprises a wire loop having a diameter in the range from about 3 mm to about 12 mm, and wherein the electrically conductive fluid comprises an isotonic irrigation fluid.
- An instrument as in claim 23, wherein the 26. surgical instrument further includes a morcellator for morcellating tissue removed by the active electrode, wherein a lumen is disposed through the elongate shaft to introduce the electrically conductive fluid into a body cavity, further comprising an aspiration source for aspirating removed tissue through the elongate shaft, and further comprising a telescope which is operably attached to the shaft, wherein the active electrode may be visualized through the scope.

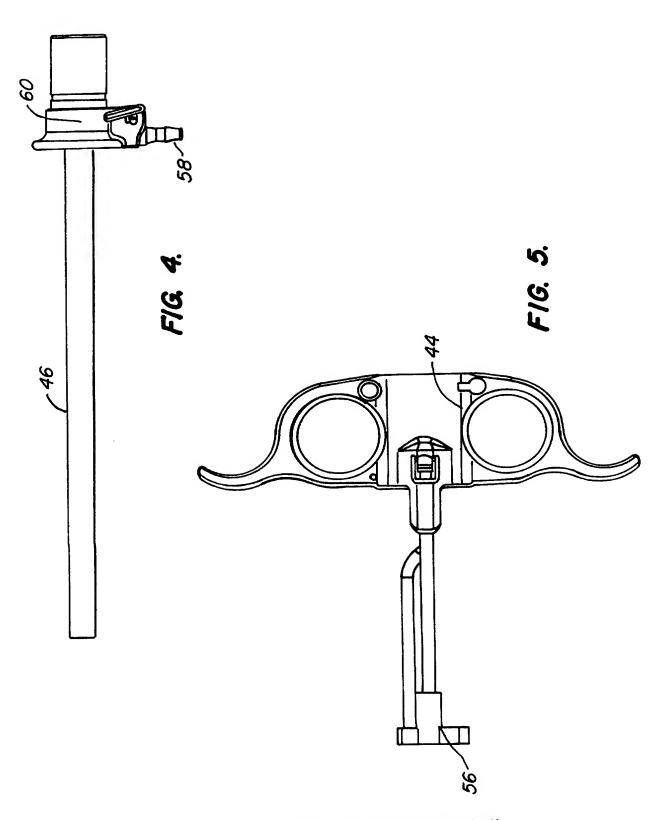
1/11



F1G. 1.

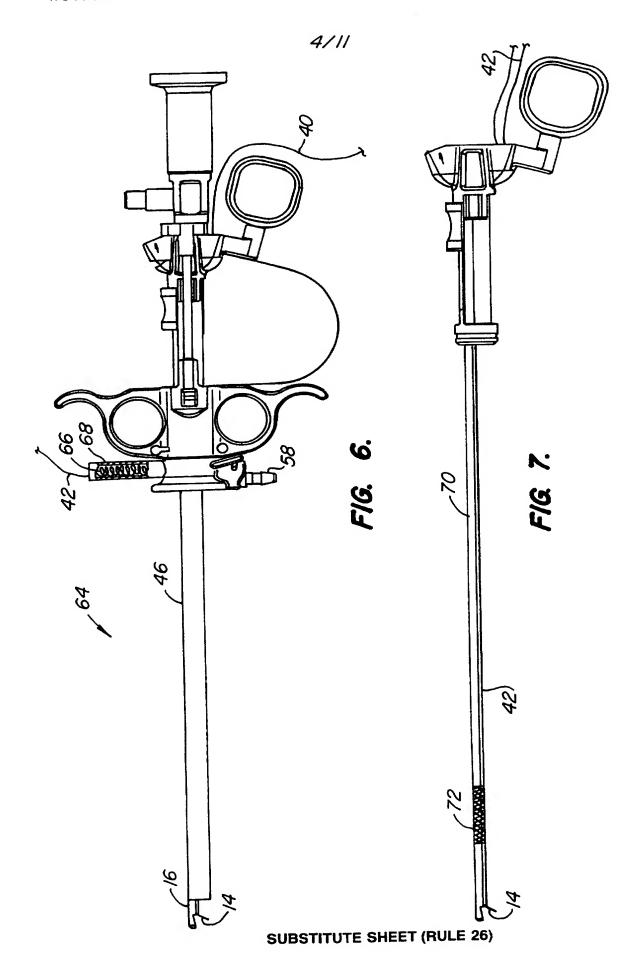


SUBSTITUTE SHEET (RULE 26)



SUBSTITUTE SHEET (RULE 26)

PCT/US97/11604



5/11

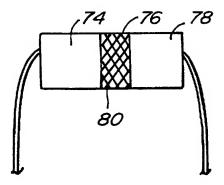
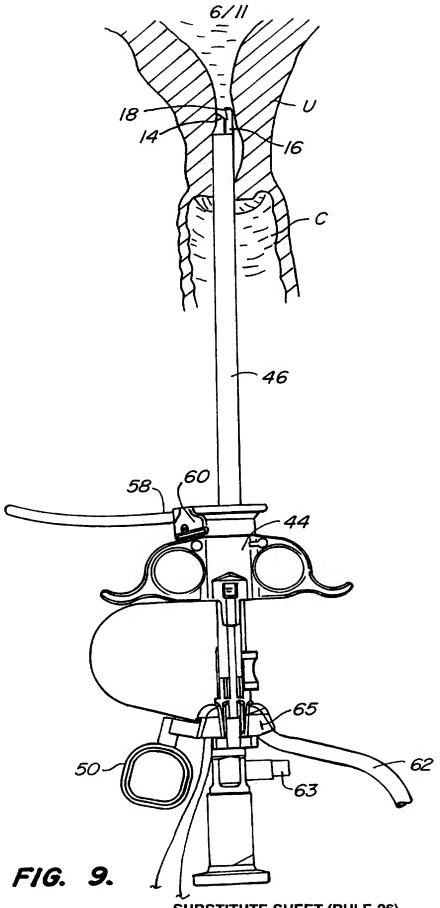
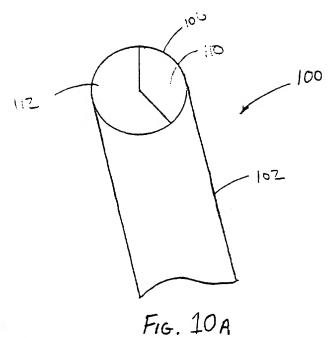


FIG. 8.

WO 98/00070 PCT/US97/11604



SUBSTITUTE SHEET (RULE 26)



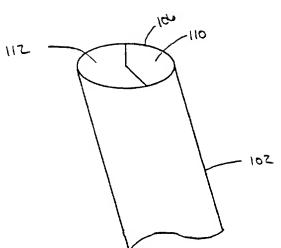
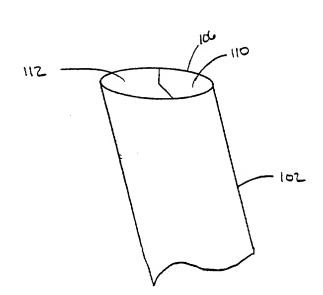
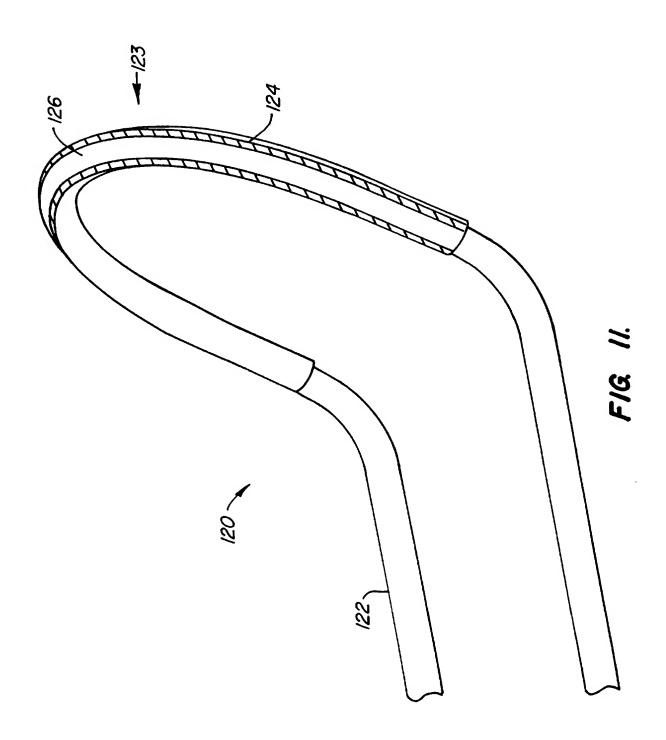


FIG. 10B



F16. 10 C



PCT/US97/11604



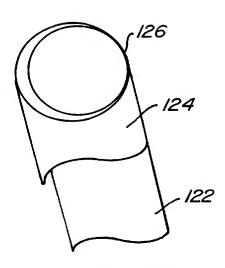


FIG. 12A.

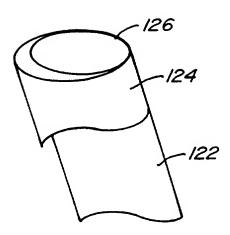


FIG. 12B.

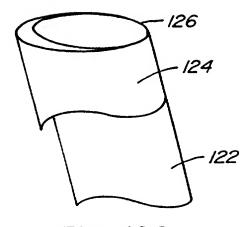
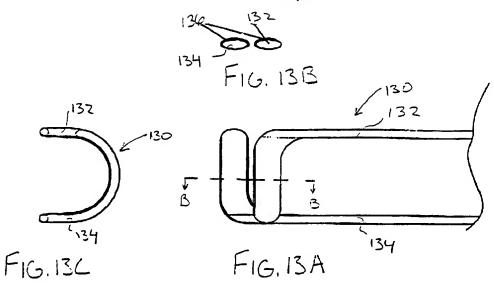
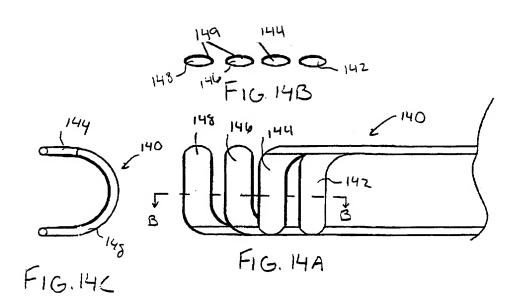
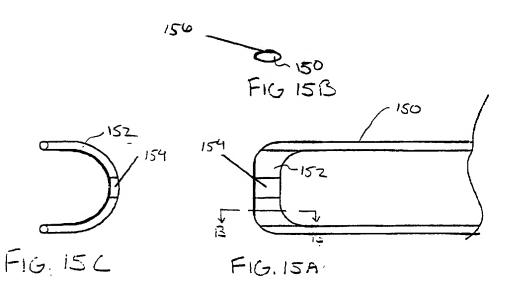
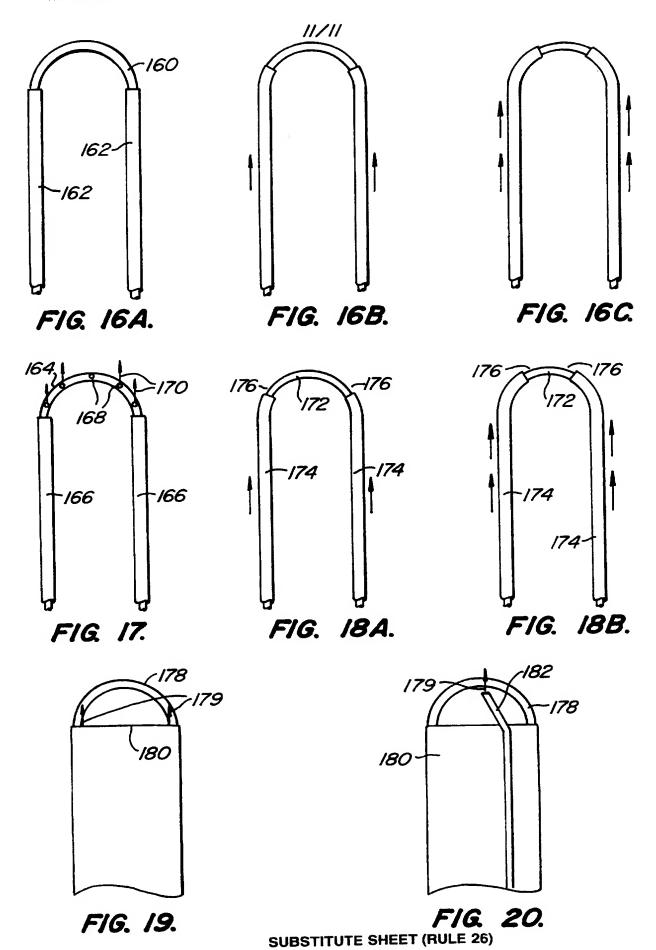


FIG. 12C. SUBSTITUTE SHEET (RULE 26)









INTERNATIONAL SEARCH REPORT

Form PCT/ISA/210 (second sheet)(July 1992)★

International application No.
PCT/US97/11604

US CL: 606/041 According to International Patent Classification (IPC) or to both national classification and IPC B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) U.S.: 606/041, 045-052; 607/098, 099 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Minimum documentation searched (classification system followed by classification symbols) U.S.: 606/041, 045-052; 607/098, 099
U.S. : 606/041, 045-052; 607/098, 099
Documentation scarched other than minimum documentation to the extent that such documents are included in the fields scarched
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
C. DOCUMENTS CONSIDERED TO BE RELEVANT
Category* Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No.
X US 4,998,527 A (MEYER) 12 March 1991, entire document. 1-4, 10, 13, 18, 20, 22
6, 8, 9, 12, 14, 15, 21, 26
X US 2,031,682 A (WAPPLER et al.) 25 February. 1936, entire document. Y 10. 17, 23, 24
Y US 5,417,697 A (WILKet al.) 23 May 1995, Fig. 6B. 5, 11, 14, 19, 25
Further documents are listed in the continuation of Box C. See patent family annex.
Special categories of cited documents: "A" document defining the general state of the art which is not considered "A" document defining the general state of the art which is not considered so the art which is not considered principle or theory underlying the invention
to be of particular relevance "X" document of particular relevance; the claimed invention cannot be considered abovel or cannot be considered abovel or cannot be considered to involve an inventive step
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as special) "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is
"O" document referring to an oral disclosure, use, exhibition or other means combined with one or more other such documents, such combination being obvious to a person skilled in the art
"P" document published prior to the international filing date but later than "&" document member of the same patent family the priority date claimed
Date of the actual completion of the international search Date of mailing of the international search report
18 AUGUST 1997 03 SEP 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks
Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230 ROSILAND S. KEARNEY Telephone No. (703) 308-2711